भारतीय मानक
Indian Standard

IS 17543 : 2021

ऊतक स्थिरीकरण स्टेशन के लिये आधारभूत आवश्यकताएँ

Basic Requirements for Tissue Embedding Station

ICS 11.140

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भारतीय मानक ब्यूरो
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Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Anatomy and Forensic Sciences Equipment Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard describes the specifications for tissue embedding station designed for embedding tissues in laboratories and pathological centers thereby allowing convenient, quick and careful paraffin embedding of tissue specimens.

The tissue embedding station is based on the embedding process by which tissues are surrounded by a medium such as paraffin wax. The orientation of tissue in melted paraffin which when solidified provides sufficient external support during sectioning by keeping intact all parts of the tissue when the sections are cut.

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

BASIC REQUIREMENTS FOR TISSUE EMBEDDING STATION

1 SCOPE

This Indian Standard specifies basic requirements for tissue embedding system which is a bench-top unit incorporated with Paraffin dispensing system and automated microprocessor based control system meant for embedding tissues in laboratories and pathological centres.

2 REFERENCE

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated:

IS No./Other Publication	*Title*
IS/IEC 61010-1 : 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 1 General requirements
IS/ISO 14971 : 2007	Medical devices — Application of risk management to medical devices
IS/IEC 61010-2-101 : 2018	Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 2-101 Particular requirements for in vitro diagnostic (IVD) medical equipment (*under print*)
IS 17533 : 2021	Paraffin Dispenser — Specification

3 COMPONENTS AND CONSTRUCTION

3.1 Tissue Embedding Unit

The unit shall include microprocessor controlled up to 5 litre paraffin reservoir, base moulds warming oven, tissue holding tank, work stage and cold plate; touch membrane pad with LED displays, lighted work stage, built-in forceps warmer, foot switch and/or push button-activated paraffin dispenser; and programmable, automatic timer controls.

3.2 Paraffin Reservoir

3.2.1 The paraffin reservoir shall be made up of Stainless steel sheet of 0.8 mm thickness with smooth finish.

3.2.2 The paraffin container equipped with temperature controller having setting range between 50 °C to 70 °C. The reservoir should have an overheat protection in case of a temperature control failure. A grid inside the paraffin reservoir shall be provided to ensure that only molten paraffin flows through the dispenser outlet nozzle to ensure trouble free embedding. An integrated filter at the junction point of dispenser and reservoir shall be provided to prevent any contamination of molten paraffin.

3.3 Paraffin Dispenser

The paraffin dispenser shall be designed for use where large volume of paraffin is required, to facilitate disposing of wax for embedding purpose**.** The dispenser shall be capable of being separately heated and should have the same temperature as the paraffin reservoir. The dispenser shall confirm to IS 17533.

3.4 Paraffin Collecting Tray

A large removable tray shall be located under the heated work area to collect excess paraffin that is drained from the surface. The paraffin collected in the tray should not be reused and emptied regularly to prevent the removable tray from sticking to guide. The tray shall be made from Stainless steel sheet of 0.8 mm thickness with smooth finish.

4 REQUIREMENTS

4.1 Quality Control and Risk Management Requirements

The device shall comply to **IS/ISO 14971**.

4.2 General Requirements

The equipment shall comply with the Requirements of **IS/IEC 61010-1** and **IS/IEC 61010-2-101**.

4.3 Safety Requirements

The device should comply with all safety requirements as described in **IS/IEC 61010-1**.

4.4 Performance Requirements

4.4.1 The tissue embedding station shall have an accurate digital thermostat with tactile membrane touch-pad for easy temperature setting and monitoring.

4.4.2 The paraffin reservoir shall have minimum 4 litre capacity and maximum 7.5 litres capacity as per customer requirements.

4.4.3 The wax bath shall be incorporated with drainage shelf, debris screen and hinged lid.

4.4.4 The work area shall be well illuminated for convenient working and shall be divided into three parts: cassette storage, working and embedding area and cold plate.

4.4.5 The heated work area shall provide a flat working surface with the excess paraffin draining under the surface into the wax bath; complete with a hand and foot switch for activating the dispensing head.

4.4.6 The cold plate shall have up to 170 sq. in. (approx. 1100 cm^2) of efficient refrigerated cooled working surface with removable stainless steel drainage tray beneath.

4.4.7 The station shall have single module design which can be electronically controlled for dependability and performance along with warming oven with removable shelf and double hinged lid for convenient access to preheated base mould:

a) The recommended dimensions of the station — The dimensions of the device shall be as agreed between manufacturer and user.
b) Temperature requirements — The recommended operating temperature range for the wax reservoirs, work surface and wax bath shall be within 40° –70 °C +/–5 °C.
c) Power input shall be 220-240 V AC, 50 Hz.

4.4.8 *Individually Heated Paraffin Dispensing System*

The paraffin dispensing system shall be incorporated with filters ensuring continuous, reproducible flow, with 8 flow rate settings (optional), Paraffin dispensing shall be set in motion manually, via foot switch or a hand operated switch.

4.4.9 *Well Illuminated Working Area*

The large work area shall be adequately illuminated to ensure convenient block removal and easy access to the cassettes.

4.4.10 *Mould Warmer and cassette bath*

The mould warming compartment shall have a wide opening for easy access and shall be capable of being heated up to 70 °C. The cassette bath shall be capable to hold more than 100 cassettes and shall be removable and easy to clean.

4.4.11 *Fully Automatic Microprocessor Control*

4.4.11.1 Provision shall be made for monitoring the temperature of mould warmer, cassette bath, working surface, paraffin reservoir, forceps heater and cold plate in real time to maintain the desired temperature through conventional or a microprocessor based system.

4.4.11.2 The menu driven microprocessor shall have an individual button for setting the parameter along a programmable timer (optional) as agreed between manufacturer and user.

4.4.12 *Cold Plate*

4.4.12.1 The cold plate should facilitate compressor cooled working surface with removable stainless steel drainage tray beneath.

4.4.12.2 The condensate from the surface of the plate should drain through special channels on either side of the cold plate area into the drip tray below without any spillage/leakage.

4.4.13 *Paraffin Dispenser Switch*

4.4.13.1 When the instrument is switched off, the dispenser nozzle casing may be wiped using a cloth moistened with a xylene substitute.

4.4.13.2 The switch shall move freely through its complete operational movement with provision for removal of accumulated was once the instrument is switched off.

5 OPERATING MANUAL

Each device shall be accompanied by an operating manual which shall contain the following information:

a) Instructions and plan for installation,
b) Operation of the apparatus, and
c) Routine maintenance and service.

6 MARKING AND PACKING

6.1 The device shall be legibly and indelibly marked at a suitable place with:

a) Unique device identification number;
b) the manufacturer’s name;
c) initials or recognized trade-mark;

d) serial number;
e) the country of manufacture; and
f) ‘Read instructions before use’.

6.2 The device may be packed as agreed to between the purchaser and the supplier.

6.3 The device shall be securely packed, in any manner, acceptable to the purchaser, so as to minimize the risk of damage in handling, transport and storage.

7 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

Organization	*Representative(s)*
Maulana Azad Medical College, New Delhi	Dr Sabita Mishra (***Chairperson***)
AIMED (Delhi)	Shri Rajesh Khatri Mrs Lalita Khatri (*Alternate*)
Dept of Forensic Medicine, Sri Ramachandra Medical College & Research Institute, Chennai	Dr P. Sampath Kumar Dr Venicatesan M. (*Alternate* I) Dr Sneha S. (*Alternate* II)
Directorate General of Health	Dr Anita Tuli Dr M. K. Wahi (*Alternate*)
Federation of Indian Chambers of Commerce and Industry (FICCI), New Delhi	Shri Vijay Kumar Dr Sandeep Sewlikar (*Alternate*)
Indian Medical Association, Delhi	Dr R. V. Asokan Dr N. V. Kamat (*Alternate*)
Kalam Institute of Health Technology, Visakhapatnam	Shri Kingshuk Poddar Shri P. Srinivasa Reddy (*Alternate* I) Shri Dilip Kumar Chekuri (*Alternate* II)
LNJN National Institute of Criminology and Forensic Science, Delhi	Dr K. P. S. Kushwaha Dr J. K. Modi (*Alternate* I) Dr Tanya Chauhan (*Alternate* II)
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National Health Systems Resource Centre, New Delhi	Shri Ajai Basil Shri Bharat Bhushan Dahiya (*Alternate*)
North Delhi Municipal Corporation Medical College, Hindu Rao Hospital, Delhi	Dr (Prof) Saudan Singh Dr Gayatri Rath (*Alternate* I) Dr Neha Gupta (*Alternate* II)
Sri Ramachandra Institute of Higher Education and Research, Chennai	Dr (Lt Col) T. Vijaya Sagar Dr S. Senthil Kumar (*Alternate* I) Dr Venkatesan M. (*Alternate* II)
VMMC & Safdarjung Hospital, New Delhi	Shri Manoj Kumar Wahi Shri G. A. Sunil Kumar Sharma (*Alternate* I) Shri Manish Kumath (*Alternate* II)
BIS Directorate General	Shri Prakash Bachani Scientist 'F' and Head (MHD) [Representing Director General (*Ex-officio*)]

Member Secretary

Dr Pradeep Dua
Scientist 'C' (MHD), BIS

Bureau of Indian Standards

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